

REMARKS

The Examiner rejected Claims 1, 4, and 10-12 under 35 U.S.C. § 102(b) as being anticipated by Patent Number 5,871,446 (Wilk). The Examiner rejected Claims 1-26 under 35 U.S.C. § 102(e) as being anticipated by Patent Number 6,478,739 (Hong). Such rejections are noted.

Claims 1, 4, and 16-18, have been amended; Claims 5 and 19 have been cancelled, without prejudice; and Claims 27 and 28 have been added. Applicant respectfully submits that Claims 1-4, 6-18, and 20-28 are allowable.

Rejection Under 35 U.S.C. § 102(b)

Addressing the Examiner's rejection of Claims 1, 4, and 10-12 under 35 U.S.C. § 102(b), Applicant respectfully submits that Wilk does not anticipate the claims of the present invention. Section 2131 of the Manual of Patent Examining Procedure describes the basis for anticipation under 35 U.S.C. § 102(b). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim. *In re Bond*, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990).

With respect to Claims 1, 4, and 10-12, the Examiner states:

In regard to claims 1, 4, and 10-12 and Wilk teaches in Fig. 14 a cancer detection system for mapping breast tissue to detect localized tissue comprising: a garment (232) (means for positioning) adapted to fit over at least one breast, a plurality of sensors (244) (means for acquiring data) mounted on the garment, wherein the plurality of sensors inherently including at least one transmitter and a plurality of receivers, wherein each of said plurality of sensors having a surface adapted to be in direct contact with at least one breast (see Fig. 14 below), the plurality of sensors being ultrasonic (col. 14, line 50); and a processing device (246) in communication with the plurality of sensors, wherein the processing device controlling the at least one transmitter, and acquiring and storing data received from the plurality of receivers.

Paper Number 20050213, Application Serial No. 10/616,559, at 2.

Claims 1 and 4

Claim 1 has been amended, but such amendment is not required to distinguish Claim 1 from Wilk, as stated below. However, the added limitations are not disclosed in Wilk. For example, the added limitation of a single transmitted signal being received by a plurality of receivers is not disclosed by Wilk. Figure 8 of Wilk illustrates a plurality of transmitting transducers **134**, each associated with a receiving transducer **142**. Wilk, Fig. 8; Col. 8, lines 50-67. Additionally, Figure 10 of Wilk illustrates a plurality of transmitting transducers **164**, each associated with a receiving transducer **168**. Wilk, Fig. 10; Col. 9, lines 39-65 ("control circuit **156** controls switching circuits **162** and **170** to energize emitting transducers **164** in a predetermined sequence and [sic] to selectively couple receiving transducers **168** in a pre-established sequence to a pressure wave or ultrasonic frequency analyzer **172**."). Nowhere in Wilk is the reception of a single transmitted signal received by a plurality of receivers disclosed or described. Accordingly, Wilk does not anticipate the limitation of a single transmitted signal being received by a plurality of receivers.

Also, Claim 1 has the added limitation that the data includes "data associated with a reflection and a time-of-flight of said signal." A word search of Wilk indicates that "time-of-flight" does not appear in that patent. Because Wilks does not disclose measuring a time of flight, Wilks cannot anticipate Claim 1 and its dependent claims, including Claim 4.

Notwithstanding that Claim 1 has been amended, Applicants respectfully submit that the rejection of the original Claim 1 for being anticipated by Wilk is not supported by the disclosure of Wilk. The Examiner asserts that the sensor vest **232** fits over at least one breast. Applicants admit that the Wilk's sensor vest **232** covers the torso of a patient and can contact the breasts; however, the vest **232** does not "fit over" the breast as the phrase is commonly used and as used within the specification. The specification states that the "sensors **18** are mounted within the sensor garment **12** such that they completely surround a breast and provide signal coverage for the entire organ." Specification, para. 33; see, also, Specification paragraphs 65 and 67 (discussing three-dimensional coverage of breast). Further, the claim includes the limitation that "each of said plurality of sensors having a surface adapted to be in direct contact with said at least one breast." As is apparent from the figures of Wilk,

the sensor vest **232** includes very few sensors **244** that would be in contact with the breasts.

Because the device of Wilk does not disclose each and every limitation of Claim 1, Wilk cannot anticipate Claim 1. Accordingly, Applicants respectfully request that the Examiner withdraw the anticipation by Wilk rejection to Claim 1 and its dependent Claim 4.

Claims 10 to 12

Claims 10-12 include means-plus-function limitations, as defined by 35 U.S.C. § 112, sixth paragraph. A means-plus-function limitation must be interpreted to cover the corresponding structure, materials, or acts in the specification and "equivalents thereof." 35 U.S.C. § 112, sixth paragraph; *see also* MPEP § 2181. The Examiner "must apply 35 U.S.C. 112, sixth paragraph in appropriate cases, and give claims their broadest reasonable interpretation, **in light of and consistent with the written description of the invention in the application.**" MPEP 2181, sub-section I, pg. 2100-220, 8th ed., rev. 2 (emphasis added).

In accordance with MPEP § 2181, it no longer is acceptable practice for the Examiner to interpret means-plus-function limitations "as reading on any prior art means or step which performed the function specified in the claim without regard for whether the prior art means or step was equivalent to the corresponding structure, material or acts described in the specification." MPEP § 2181, pg. 2100-220 (emphasis added). The current practice is that "the application of a prior art reference to a means or step plus function limitation requires that the prior art element perform the identical function specified in the claim." MPEP § 2182, pg. 2100-227. "However, if a prior art reference teaches identity of function to that specified in a claim, then under *Donaldson* an examiner carries the initial burden of proof for showing that the prior art structure or step is the same as or equivalent to the structure, material, or acts described in the specification which has been identified as corresponding to the claimed means or step plus function." *Id.* (emphasis added). The MPEP further states "The 'means or step plus function' limitation should be interpreted in a manner consistent with the specification disclosure." *Id.*

For making a *prima facie* case of equivalence for a means-plus-function limitation, the MPEP states

If the examiner finds that a prior art element

- (A) performs the function specified in the claim,
- (B) is not excluded by any explicit definition provided in the specification for an equivalent, and
- (C) is an equivalent of the means-(or step-) plus-function limitation,

the examiner should provide an explanation and rationale in the Office action as to why the prior art element is an equivalent.

MPEP § 2183, pg. 2100-228. With respect to the third element above, the prior art element is an equivalent, the MPEP states that a factor supporting such a conclusion is "(D) the prior art element is a structural equivalent of the corresponding element disclosed in the specification." MPEP § 2183, pg. 2100-228. The MPEP further requires, in order to find equivalence, that "the prior art element performs the function specified in the claim in substantially the same manner as the function is performed by the corresponding element described in the specification." MPEP § 2183, pg. 2100-228 (emphasis added).

Accordingly, it is necessary to consider the specification in determining the scope of the rejected claims. The specification states that the "sensor garment **12** provides the function of positioning the sensors **18** against the breast." Specification, para. 39. The sensor vest **232** of Wilk does not perform the same function as the sensor garment **12**, illustrated in Figures 1, 7, 7a, 7b, and 9 to 11. The sensor vest **232** covers the torso of a patient and is not able to envelop or cover at least one breast as disclosed by Applicants.

The specification states that "the local processing device **20** provides the function of acquiring the data received by the sensors **18**. The remote processing device **22** provides the function of processing the data acquired by the local processing device **20**." Specification, para. 39. The local processing device **20** is described in the specification as being "employed for system control, data collection, user interface, and

communication," and the specification provides details as to the how the local processing device **20** accomplishes this. Specification, para. 35. The Examiner asserts that the function of acquiring data is accomplished by the sensors **244** discloses by Wilk. Applicants respectfully disagree. The sensors **244** disclosed by Wilk do not perform the functions as described by Applicants in the specification. Further, Wilk does not disclose any structure corresponding to the claimed functions.

Applicants respectfully submit that Claims 10-12 are not anticipated by Wilk because Wilk does not disclose any equivalent structures corresponding to those disclosed in Applicants' specification, and, therefore, Wilk does not teach every element of the claimed invention. Accordingly, Applicants respectfully request that the Examiner withdraw his rejection of Claims 10-12.

Requirements for Rejecting Claims

Initially, Applicants wish to point out that Claims 1 to 26 of the Application include many limitations, each one of which Applicants consider important to the patentability of their invention. The MPEP provides guidance to examiners in rejecting claims. In particular, the MPEP states that omnibus rejections should be avoided. MPEP § 707(d), at 700-113, 8th ed., rev. 1. Further, the MPEP states: "A plurality of claims should never be grouped together in a common rejection, unless that rejection is equally applicable to all claims in the group." *Id.* This is in keeping with the goal of examination, which is "to clearly articulate any rejection early in the prosecution process so that the applicant has the opportunity to provide evidence of patentability and otherwise reply completely at the earliest opportunity." MPEP § 706, at 700-17.

Contrary to the above requirements, the Examiner has rejected Claims 1-26 without addressing the unique limitations of each claim. Applicants remind the Examiner that in order to support a rejection, each and every limitation of each claim must be found, either expressly or inherently, in the prior art. *See* MPEP 2131 and 2143. Applicants respectfully submit that the Examiner has not addressed each claim and each element and limitation of each claim as required by the MPEP. Accordingly, it is respectfully requested that the Examiner withdraw the rejections or, in the alternative, address each claim and each element as required. In the latter case, because such restatement of the rejection is necessary to complete the statement of

the grounds for rejection (see MPEP 706.07), it is respectfully submitted that it would be inappropriate to make the next Examiner's action final, unless, of course, the next action is a Notice of Allowance.

Notwithstanding the above concerns and in an attempt to anticipate the Examiner's complete statement of the grounds for rejection, Applicants herein address the rejected claims and identify at least one element and/or limitation not found in the prior art, as appropriate.

Also, the Examiner makes statements in the grounds for rejection that are not linked to any particular claim. One such statement is "Hong further teaches that the system includes a coupling agent for providing connectivity between the sensors and at least one breast (see Fig. 4 item 18)." Paper Number 20050213, Application Serial No. 10/616,559, at 4. Applicants note that the device of Hong requires at least one bladder **12** and that Hong does not disclose a device that operates without a bladder. See Hong, Col. 3, lines 57; independent Claims 1, 20 (which require a bladder). In other words, Hong teaches away from not using a bladder. Applicants specification does not disclose a bladder as a coupling agent **26**, see Specification, para. 49, nor do the independent claims of the Application require a bladder, which is disclosed as a required element of Hong. Accordingly, Applicants respectfully submit that the Examiner's above-quoted comment does not support the rejection of any claim.

Rejection Under 35 U.S.C. § 102(e)

Addressing the Examiner's rejection of Claims 1-26 under 35 U.S.C. § 102(e), Applicant respectfully submits that Hong does not anticipate the claims of the present invention. Section 2131 of the Manual of Patent Examining Procedure describes the basis for anticipation under 35 U.S.C. § 102(b). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim. *In re Bond*, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990).

With respect to Claims 1-26, the Examiner states:

Hong teaches a cancer detection system for mapping breast tissue to detect localized tissue comprising: a bra-type garment (2) (means for positioning) adapted to fit over at least one breast, a plurality of sensors (28) (means for acquiring data) mounted on the garment, wherein the plurality of sensors inherently including at least one transmitter and a plurality of receivers, wherein each of the plurality of sensors having a surface adapted to be in direct contact with at least one breast (see Fig. 1 below), the plurality of sensors being ultrasonic (col. 4, line 55); and a processing device (36) in communication with the plurality of sensors, wherein the processing device controlling the at least one transmitter, acquiring and storing data received from the plurality of receivers, programmed to check the time-of-flight for each detected signal.

Hong further teaches that the system includes a coupling agent for providing connectivity between the sensors and at least one breast (see Fig. 4 item 18).

The specific limitations of remote processing are well known in the art. Furthermore, breast tissue examination device of Hong inherently teaches the steps and structures for constructing a chronological profile of the patient's tissue.

Paper Number 20050213, Application Serial No. 10/616,559, at 3-5.

Prior Art: Hong

Hong discloses "a device that provides an ultrasonic signature of the breast tissue by transmitting ultrasonic waves from an ultrasonic transmitting transducer through the breast to **an** ultrasonic receiving transducer." Hong, Col. 1, lines 50-54 (emphasis added). An important feature of the Hong device are the "at least two mutually opposed ultrasound transducer arrays." Hong, Col. 6, lines 26-27. "By 'mutually opposed' it is meant that the transducer arrays are aligned in a facing configuration such that an ultrasonic pulse from a transmitting transducer in the first transducer array **25** is received by a receiving transducer in the second transducer array **26** (or vice-versa) after the pulse has passed through the intervening breast tissue." *Id.* at lines 28-34. The importance of the one-to-one correspondence of transmitter and receiver is further stated by Hong with the statement that "there is preferably a one-to-one correspondence of each transducer pair of transmitting and receiving arrays **25, 26.**" Hong, Col. 9, lines 46-48.

Hong teaches away from more than one receiver receiving a signal from a single transmitter. Hong states:

In some embodiments, all of the transducers **28** within the receiving array **26** can be operated at the same time, and thus, more than one receiving transducer may detect the ultrasonic waves from the transmitting transducer. However, in such embodiments, the signal switch **35** can select the specific receiving transducer matched with its corresponding transmitting transducer with information relating to the addresses of the transducers from microprocessor **36**. In other embodiments, only the receiving transducer that is matched with the transmitting transducer is operated at the time the transmitting transducer is signaled. In either case, there is preferably a one-to-one correspondence of each transducer pair of transmitting and receiving arrays **25**, **26**.

Hong, Col. 9, lines 35-48.

Independent Claim 1

The Examiner asserts that "each of the plurality of sensors having a surface adapted to be in direct contact with at least one breast (see Fig. 1 below)." Paper Number 20050213, Application Serial No. 10/616,559, at 3. Hong does not illustrate the sensors **28** in Figure 1. Also, in the written description, Hong does not make any statements with respect to the sensors **28** and Figure 1. Hong, Col. 3, lines 3-42. However, with respect to Figure 4, Hong discloses a bladder **12** disposed between the "breast **14** and the measurement apparatus **13** mounted to the inner surface **8** of the shell **4**." Hong, Col. 3, lines 58-61. A close reading of Hong does not provide any indication that Hong discloses the sensors **28** "having a surface adapted to be in direct contact with said at least one breast." This is further supported by preferred arrangement of the sensors **28** in which the sensor faces are not positioned parallel to the breast surface. See Hong, Figs. 48, 9a, 9b, and 12.

Notwithstanding the above, independent Claim 1 has been amended to add the limitation that "each one of said at least one transmitter transmitting a signal and more than one of said plurality of receivers receiving said signal." As stated above, Hong discloses a single transmitter and single receiver pair, that is, a single receiver responsive to the signal from a single transmitter. Further, Hong teaches away from a plurality of receivers being responsive to a single transmitter by stating that any signal received by more than one receiver is not used and is discarded. Hong, Col. 9, lines 35-43. In light of the other limitations of Claim 1 not anticipated by Hong, the amendment to Claim 1 is not required to distinguish Claim 1 from Hong, but the limitation is made to clarify the bounds of the invention as claimed in Claim 1.

The Examiner also asserts that "the plurality of sensors inherently including at least one transmitter and a plurality of receivers." In the discussion below with respect to Claims 8, 15, 20, and 26, Applicants cite the MPEP rules with respect to an examiner making findings of inherency. To paraphrase that discussion, a limitation is inherent if it is "necessarily present." See MPEP 2112, pp. 2100-54-55. A plurality of sensors means that there is more than one sensor. It is no more inherent that the more than one sensor be all transmitters than it is inherent for the more than one sensor to be all receivers. The more than one sensor could also include just one transmitter and just one receiver. In other words, the phrase "plurality of sensors" cannot inherently include "at least one transmitter and a plurality of receivers" as asserted by the Examiner because a plurality of sensors can include a multitude of configurations of transmitters and receivers.

According, Applicants respectfully submit that Hong does not anticipate amended Claim 1 because Hong does not disclose each and every limitation of the claim. Further, Claims 2-4 and 6-9 are also in condition for allowance as depending from an allowable base claim.

Dependent Claim 6

The Examiner makes statements in the grounds for rejection that are not linked to any particular claim. One such statement is "The specific limitations of remote processing are well known in the art." Paper Number 20050213, Application Serial No. 10/616,559, at 5. The Examiner has not identified to which claims this remark applies. Neither is it apparent to the Applicants what this statement means with respect to being grounds for rejecting any of the claims.

Although the Examiner has not identified any specific claim associated with the above-quoted comment, Applicants assume that the Examiner is referring to Claim 6, which describes a distributed processing system with a local processing device performing specified operations and a remote processing device performing other specified operations. In order for a prior art reference to anticipate a claim, each and every limitation of that claim must be found, either explicitly or inherently, in the prior art reference.

Because Hong does not disclose a distributed processing system with the limitations as claimed in Claim 6 and because the Examiner has not shown that Hong discloses the limitations associated with the elements of Claim 6, Applicants respectfully request the Examiner to withdraw the rejection of Claim 6.

Independent Claim 10

As stated above, Claim 10 includes means-plus-function limitations, which must be interpreted "**in light of and consistent with the written description of the invention in the application.**" MPEP 2181, sub-section I, pg. 2100-220, 8th ed., rev. 2 (emphasis added).

Claim 10 includes the limitations of "a means for acquiring data by utilization of said plurality of sensors; and a means for processing acquired data." The specification states that "the local processing device **20** provides the function of acquiring the data received by the sensors **18**. The remote processing device **22** provides the function of processing the data acquired by the local processing device **20**." Specification, para. 39. The specification goes into great detail in describing the operations performed by the local processing device **20** and the remote processing device **22**, including multiple sensors **68, 72, 76, 80** receiving the signal from a single transmitting device **64**. See Specification, para. 55; FIG. 7 & 11.

The use of multiple receiving sensors for each transmitting sensor is substantially different than that disclosed in Hong, which discloses a one-to-one correspondence between receiving and transmitting sensors. Applicants respectfully submit that Claim 10 includes elements not disclosed by Hong. Applicants respectfully submit that Claim 10 is not anticipated by Hong because Hong does not disclose any equivalent structures corresponding to those disclosed in Applicants' specification, and, therefore, Hong does not teach every element of the claimed invention. Accordingly, Applicants respectfully request that the Examiner withdraw his rejection of Claim 10. Further, Claims 11-15 are also in condition for allowance as depending from an allowable base claim.

Independent Claim 16

Independent Claim 16 has been amended to add the limitation that "said processing device responsive to a signal transmitted by one of said plurality of transmitting sensors received by more than one of said plurality of receiving sensors." Hong discloses "a one-to-one correspondence of each transducer pair." Hong, Col. 9, lines 46-47. Further, Hong teaches away from having more than one receiver receiving a signal from a transmitter. Hong, Col. 9, lines 35-48. The added limitation of Claim 16 is not disclosed by Hong.

According, Applicants respectfully submit that Hong does not anticipate Claim 16 because Hong does not disclose each and every limitation of the claim. Accordingly, Claims 17, 18, 20, and 21 are also in condition for allowance as depending from an allowable base claim.

Independent Claim 22

Independent Claim 22 includes the step of "receiving said ultrasonic signal by an array of receivers." Hong discloses "a one-to-one correspondence of each transducer pair." Hong, Col. 9, lines 46-47. Further, Hong teaches away from having more than one receiver receiving a signal from a transmitter. Hong, Col. 9, lines 35-48. Applicants point out that the clear language of Claim 22 requires that the more than one receiver receive an ultrasonic signal from a transmitter. According, Applicants respectfully submit that Hong does not anticipate Claim 22 because Hong does not disclose each and every limitation of the claim. Accordingly, Claims 23-26 are also in condition for allowance as depending from an allowable base claim.

Dependent Claims 8, 15, 20, and 26

Notwithstanding that Claims 8, 15, 20, and 26 are allowable for depending from an allowable base claim, Applicants respectfully submit that Claims 8, 15, 20, and 26 include limitations not anticipated by the cited prior art. The Examiner states that the "breast tissue examination device of Hong inherently teaches the steps and structures for constructing a chronological profile of the patient's tissue." Paper Number 20050213, Application Serial No. 10/616,559, at 5. Although the Examiner has not so identified his comment, Applicants assume the Examiner is referring to Claims 8, 15, 20, and 26 with this comment. Applicants respectfully disagree with the

Examiner's assertion. Section 2112, subsection IV of the MPEP provides guidance on an acceptable anticipation rejection based on inherency. The MPEP states: "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." MPEP, 2112, pg. 2100-54. The MPEP further states

"To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' "

MPEP 2112, pp. 2100-54-55 (citing *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)). Applicants point out that many diagnostic methods, such as that disclosed in Hong, do not require or necessarily have the capability for constructing a chronological profile.

Applicants respectfully request the Examiner provide a basis in fact and/or technical reasoning to reasonably support his assertion of inherency, as required by MPEP 2112, subsection IV , pg. 2100-55 ("In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.").

Because the Examiner has not met the necessary burden of showing anticipation, Applicants respectfully request the Examiner withdraw the rejection of Claims 8, 15, 20, and 26.

Specification Amendment

Paragraph 54 of the specification has been amended to correct a typographical error. The word "transmitted" in the specification has been replaced with the word "transmitter."

Other Amended and Cancelled Claims

The limitations of Claim 5 have been incorporated into amended Claim 4 as part of a Markush group. The scope of amended Claim 4 is the same as the scope of

the original Claim 4 and the original Claim 5. Claim 5 has been cancelled as being duplicative.

The limitations of Claim 19 have been incorporated into amended Claims 17 and 18 as part of a Markush group. The scope of amended Claims 17 and 18 are the same as the scope of the original Claim 19 and the original Claims 17 and 18 . Claim 19 has been cancelled as being duplicative.

New Claims

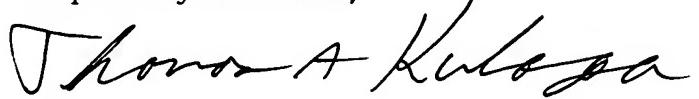
Claims 27 and 28 have been added to the application. The limitations of these new claims are fully disclosed in the original specification and do not constitute new matter.

Conclusion

In view of the amendment of Claims 1, 4, and 16-18, the cancellation of Claims 5 and 19, without prejudice, and the addition of Claims 27 and 28, it is believed that the above-identified patent application is in a condition for the issuance of a Notice of Allowance. Such action by the Examiner is respectfully requested. If, however, the Examiner is of the opinion that any of the drawings or other portions of the application are still not allowable, it will be appreciated if the Examiner will telephone the undersigned to expedite the prosecution of the application.

Please charge any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 16-1910 (28337.00).

Respectfully submitted,



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